

*REMARKS/ARGUMENTS**The Present Invention*

The invention is directed to a method of promoting the regression of a cancer in a mammal.

The Pending Claims

Claims 1-40 are pending of which claims 1-22 are withdrawn and claims 23-40 are under examination.

The Office Action

The restriction requirement was made final. Claims 36, 39, and 40 are rejected under 35 U.S.C. Section 112, second paragraph, as allegedly indefinite. Claims 23-35, 37, and 38 are rejected under Section 102 (a) as allegedly anticipated by Dudley et al., *J. Immunotherapy* 25: 243-251 (2002) (hereinafter Dudley) and under Section 102 (e) as allegedly anticipated by WO 03/004625 (hereinafter the '625 application). Claims 23, 35, 36, 39, and 40 are rejected under Section 103 (a) as allegedly unpatentable over Dudley or the '625 application, each in view of Seiter et al., *J. Immunotherapy* 25: 252-263 (2002) (hereinafter Seiter). Claims 23-35, 37, and 38 are rejected as allegedly unpatentable over Dudley or WO 97/05239 (hereinafter the '239 application) in view of U.S. Patent 6,447,767 (hereinafter the '767 patent). Claims 36, 39, and 40 are rejected as allegedly unpatentable over Dudley or the '239 application in view of the '767 patent in view of Seiter. Reconsideration of the rejections is hereby requested.

The Amendments to the Specification and the Claims

The specification has been amended to include the amino acid sequences of MART-1 and the gp100: 209-217 (210M) peptide, which sequences are incorporated into the specification of the instant application by reference to Kawakami et al., *Proc. Natl. Acad. Sci. U.S.A.* 91: 3515-3519 (1994) (a copy of which is attached; see paragraph [0033] on page 9 of the instant application) and Dudley et al., *J. Immunotherapy* 24: 363-373 (2001) (see paragraph [0003] on page 1 of the instant application), respectively. Specifically, the amino acid sequence of MART-1 is disclosed in Figure 1 of the Kawakami reference, while the

amino acid sequence of the gp100: 209-217 (210M) peptide is disclosed in lines 12 and 13 of the 2nd paragraph of the right column of page 364 of the Dudley (2001) reference. A sequence listing containing these sequences, as well as a statement regarding the incorporation-by-reference of material submitted electronically, also has been added to the specification.

Claim 23 has been amended to recite that the autologous T cells were previously isolated and selected for, followed by one cycle of rapid expansion using irradiated allogeneic feeder cells, OKT3 antibody, and IL-2, or were previously isolated, selected for, and modified, followed by one cycle of rapid expansion, which is supported by the specification at, for example, page 8, lines 5-7. Claims 36, 39, and 40 have been amended to include reference to a sequence of the sequence listing attached hereto. No new matter has been added by way of the amendments.

Request for Reconsideration of the Restriction Requirement and Discussion of the Restriction Requirement That Was Improperly Made Final

The Office Action indicates that the citation of the '239 application as a basis for the Restriction Requirement set forth in the Office Action dated May 1, 2007, was a typographical error and that the citation should have been the '625 application. The Office Action nonetheless makes final the Restriction Requirement.

The Office Action making final the Restriction Requirement is improper, since Applicants did not have an opportunity to Reply to the Restriction Requirement in view of the correct citation. Furthermore, as mentioned below, the '625 application is not prior art to the instant application, since the invention was conceived of and reduced to practice prior to the effective filing date of the '625 application. Accordingly, the '625 application cannot be a basis for destroying the unity of invention of the instant application. Applicants therefore request that the Restriction Requirement be withdrawn, such that claims 1-40 are examined together.

Discussion of the Indefiniteness Rejection

The Office Action rejects claims 36, 39, and 40 as allegedly indefinite for not specifying the sequence of "MART-1" or "gp100." Claims 36 and 39 have been amended to

reference SEQ ID NO: 1, which is the amino acid sequence of MART-1, while claim 40 has been amended to reference SEQ ID NO: 2, which is the amino acid sequence of the gp100:209-217 (210M) peptide. In view of the amendments to the claims, the rejection is moot. Applicants therefore request the withdrawal of the rejection.

Discussion of the Anticipation Rejections

A. Dudley

The Office Action rejects claims 23-35, 37, and 38 under Section 102 (a) as allegedly anticipated by Dudley. According to Exhibit A, the publication date of Dudley is May-June 2002. While the exact publication date has not been established, it will be assumed, *arguendo*, that Dudley published as early as May 1, 2002. As supported by the Declaration under 37 C.F.R. Section 131 of Mark E. Dudley, a copy of which is attached hereto, the invention was conceived of and reduced to practice before July 2, 2001. Therefore, even if Dudley published on May 1, 2002, the invention was conceived of and reduced to practice before the publication of Dudley. Accordingly, Dudley is not prior art to the instant application. In view of the foregoing, the rejection under Section 102 in view of Dudley cannot stand. Applicants therefore request that the rejection be withdrawn.

B. The '625 Application

The Office Action rejects claims 23-35, 37, and 38 under Section 102 (e) as allegedly anticipated by the '625 application. The '625 application published on January 16, 2003, indicating a priority date of July 2, 2001. As supported by the Declaration under 37 C.F.R. Section 131 of Mark E. Dudley, the invention was conceived of and reduced to practice before July 2, 2001. Accordingly, the '625 application is not prior art to the instant application. In view of the foregoing, the rejection under Section 102 in view of the '625 application cannot stand. Applicants therefore request that the rejection be withdrawn.

Discussion of the Obviousness Rejections

A. Dudley in view of the '625 application and Seiter

The Office Action rejects claims 23, 35, 36, 39, and 40 under Section 103 (a) as allegedly unpatentable over Dudley, the '625 application, and Seiter. As discussed herein,

the invention was conceived of and reduced to practice before the publication of Dudley and the indicated priority date of the '625 application. According to Exhibit B, the publication date of Seiter, like Dudley, is May-Jun 2002. While the exact publication date has not been established, it will be assumed, *arguendo*, that Seiter published as early as May 1, 2002. As the invention was conceived of and reduced to practice before July 2, 2001 (as discussed above), which is before the publication date of Seiter, Seiter is not prior art to the instant application. In view of the foregoing, none of Dudley, the '625 application, and Seiter are prior art to the instant application, such that the rejection in view of these references cannot stand. Applicants therefore request that rejection is withdrawn.

B. Dudley or the '239 application in view of the '767 Patent

Claims 23-35, 37, and 38 are rejected as allegedly unpatentable over Dudley or the '239 application in view of the '767 patent. The rejection is traversed, because Dudley, as discussed above, is not prior art to the instant application, the '239 application, as stated in the Office Action on page 6, does not teach or suggest a treatment protocol comprising administering non-myeloablative lymphodepleting chemotherapy, and the '767 patent does not teach each and every element of the claim as amended herein. Therefore, the rejection cannot stand. Applicants therefore request that rejection is withdrawn.

C. Dudley or the '239 application in view of the '767 Patent and Seiter

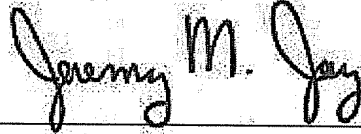
The Office Action rejects claims 36, 39, and 40 as allegedly unpatentable over Dudley or the '239 application in view of the '767 patent in further view of Seiter. The rejection is traversed, because, as discussed above, neither Dudley nor Seiter are prior art to the instant application. Also, as discussed herein, the '239 application does not teach or suggest a treatment protocol comprising administering non-myeloablative lymphodepleting chemotherapy. Further, the '767 patent does not teach each and every element of the claim as amended herein. In view of the foregoing, the rejection cannot stand. Applicants therefore request that the rejection be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the

prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

A handwritten signature in cursive script that reads "Jeremy M. Jay". The signature is written in dark ink and is positioned above a horizontal line.

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